Summary and classification of the key results of the "STEP.De exercise therapy for depression" project

In its decision of March 22, 2024, the Innovation Committee of the Federal Joint Committee (G-BA) amended its decision of September 20, 2023, which provided for the immediate transfer of exercise therapy to the standard care of statutory health insurance within 12 months (see press release of March 22, 2024). This change was made in response to a supplementary statement with erratum, that we submitted to the G-BA due to increasing uncertainty regarding the results of the long-term course.

We have summarized the key results of the project here once again in a generally understandable way. The detailed reports can be found on the G-BA website here.

In the STEP.De project, the study participants were assigned to either psychotherapy or exercise therapy. The exercise therapy group was offered exercise therapy for 4 months. During these four months, there was an improvement in depression in both groups (by -5-85 points in the exercise therapy group and by -5-81 points in the psychotherapy group) on the Beck Depression Inventory, which corresponds to a clinically significant effect. Over these four months, exercise therapy was equivalent and not inferior to psychotherapy.

At the end of the 4-month exercise therapy programme, psychotherapists determined the need for further treatment. Only 22% of the STEP exercise therapy participants started further psychotherapy. In the psychotherapy group, 77% of the study participants continued their psychotherapy.

As reported in the supplementary statement, long-term follow-up examinations (6 months and 12 months after the end of the 4-month exercise therapy) showed no increase in depression in the exercise therapy group, but an increasing statistical uncertainty with regard to the equivalence of exercise therapy compared to psychotherapy. After 6 months, we measured depression using the Beck Depression Inventory and additionally the Hamilton Depression Scale. Exercise therapy was (just) not equivalent to psychotherapy on the Beck Depression Inventory, but was equivalent and not inferior on the Hamilton Scale. However, 12 months after its completion, exercise therapy was no longer equivalent to psychotherapy; the study participants in the psychotherapy group were numerically 1.55 points better than those in the exercise therapy group on the Beck Depression Inventory, which can be attributed to a further improvement in the psychotherapy group.

Exercise therapy was more cost-effective; during the 4 months of sports therapy, we saw cost savings of about €300 per patient compared to psychotherapy. In the period up to 6 months after the end of exercise therapy, we saw a further average cost saving of about €700 per patient.

Classification and future directions

Exercise therapy is now considered an evidence-based treatment option for mental health conditions from the depression spectrum (e.g. <u>Noetel et al., 2024</u>; <u>Heissel et al. 2023</u>; <u>Singh et al., 2023</u>) and is also recommended as a treatment option in medical guidelines (e.g. <u>S3</u> <u>Leitlinie Nationale Versorgungs-Leitlinie Unipolare Depression</u>).

However, based on our supplementary statement, the G-BA believes that more research is needed before exercise therapy can be included in standard care as an independent and sole form of therapy for depressive disorders: "The project was able to gain important new insights into the question of whether exercise therapy accompanied by psychotherapists can partially replace psychotherapy alone. However, the results should be confirmed by further research".

We are currently working on further research approaches to this question.

However, the chairman of the committee, Prof. Hecken, is already pointing out possible implementation approaches: "We very much hope that individual components of the new care approach will already be used, despite the selective need for further research. This could be done, for example, through selective contracts."

We welcome the call by the chairman of the G-BA's Innovation Committee to the health and long-term care insurance funds to implement components of STEP.De exercise therapy now by means of selective contracts.

You can access the project website here.

Prof. Dr. Michael Rapp, Dr. Andreas Heißel, Prof. Dr. Stephan Heinzel. Status: 19.04.2024